



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,871	09/19/2000	Francois Mach	EGYP 3.0-009	5326

7590 10/20/2004

IVOR R. ELRIFI, ESQ.
MINTZ LEVIN
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,871

Applicant(s)

MACH, FRANCOIS

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,15-20,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,15-20,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2004 has been entered.

The outstanding rejection under 35 USC 102(b) is withdrawn in view of the amendments filed July 27, 2004.

Claims 1-3, 5-6, 15-20, and 38-39 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-6, 15-20, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanislaus et al. (Neuroscience Letters, 1999;269:71-74) in view of Steiner et al. (Rheumatology, 1999 ;38 :202-213).

Stanislaus et al. teaches a method of inhibiting the proinflammatory cytokines, TNF, IFN γ , a cytokine mediates the MHC class II expression immunoresponse, in

Art Unit: 1617

animal model of multiple sclerosis (MS) by administering lovastatin intradermally (See the abstract and page 71, last paragraph bridging page 72, col. 1). Stainislaus et al. also suggests that lovastatin may be significant in therapeutic management of MS (See page 74, col. 1, last paragraph).

Stainislaus et al. does not expressly teach the dosage of lovastatin employed as 10 to 80 or 20 to 40 mg per day. Stainislaus et al. does not expressly teach the administration made daily. Stainislaus et al. does not expressly teach inhibition of IFN γ be effective in rheumatoid arthritis patients.

Steiner et al. teaches the role of IFN γ production in rheumatoid arthritis (See particularly the abstract, page 204, col. 1, last paragraph – page 206, col. 2, first paragraph, also Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lovastatin in the herein claimed dosage and regimen. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lovastatin in rheumatoid arthritis patients.

One of ordinary skill in the art would have been motivated to employ lovastatin in the herein claimed dosage and regimen. The optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ lovastatin in rheumatoid arthritis patients to modulate the MHC class II expression in rheumatoid arthritis (RA) patients. Since IFN γ is important in pathogenesis in RA patients, and lovastatin is known to inhibit IFN γ , employing lovastatin to RA patients would be

Art Unit: 1617

reasonably expected to be effective in blocking IFN γ and inhibit the the MHC class II expression mediated inflammation.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5-6, 15-20, and 38-39 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617

